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10/572,853	02/09/2007	Gen-Ichiro Soma	80246(302741)	9265
21874	7590	10/27/2010	EXAMINER	
EDWARDS ANGELI, PALMER & DODGE LLP			MI, QIUWEN	
P.O. BOX 55874			ART UNIT	PAPER NUMBER
BOSTON, MA 02205			1655	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,853	<b>Applicant(s)</b> SOMA ET AL.
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 05 October 2010.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 12-14, 16-22, 26-29 and 33-38 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 12-14, 16-22, 26-29 and 33-38 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 22 March 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- 1) Certified copies of the priority documents have been received.
- 2) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date: \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant's amendment in the reply filed on 10/5/2010 is acknowledged. Claims 1-11, 15, 23-25, and 30-32 are cancelled. Claims 12-14, 16-22, 26-29, and 33-38 are pending.

**Claims 12-14, 16-22, 26-29, and 33-38 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

**Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-14, 16-22, 26-29, and 33-38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Mulyowidarso et al (Mulyowidarso et al, The microbial ecology of soybean soaking for tempe production, International Journal of Food Microbiology, 8 (1989) 35-46), and Inagawa et al (Homeostasis as regulated by activated macrophage. II. LPS of plant origin other than wheat flour and their concomitant bacteria, Chem. Pharm. Bull. 40 (4) 994-997, 1992), and further in view of Matsuo et al (Matsuo et al, Suppression of plasma cholesterol elevation by Okara tempe in rats, Biosci Biotech Biochem 57 (7): 1188-1190, 1993).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 35/27/2010, repeated below, slightly altered to take into consideration Applicant's amendment filed on 10/5/2010. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Mulyowidarso et al teach soybean tempe is a fermented food (thus a fermented edible plant extract) (thus a food containing the fermented plant extract, thus the limitation of claims 18 and 21 is met) (thus contains polysaccharide, see Inagawa et al below) that is consumed as a staple item in Indonesia and several other countries in South East Asia (page 35, 1<sup>st</sup> paragraph). Mulyowidarso et al also teach soybeans soaked in tap water for 24 to 36 h at 20, 30 or 37 degrees C underwent a natural fermentation that was characterized by the growth of microorganisms to  $10^8$ - $10^{10}$  cfu/ml (depending on temperature) and a reduction of pH from 6.5 to 4.5 (thus fermented, thus contains no component derived from an animal). Lactobacillus casei, Streptococcus faecium, Staphylococcus epidermidis and Streptococcus dysgalactiae dominated the fermentation but, significant contributions were also made by Klebsiella pneumoniae, Klebsiella ozaenae, Enterobacter cloacae, Enterobacter agglomerans (the same as Pantoea agglomerans, see the Definition of Pantoea agglomerans from Wikipedia (Definition of Pantoea agglomerans from Wikipedia, accessed on 3/16/2010, pp. 1) (thus facultative anaerobic gram-negative bacterium, bacillus), Citrobacter diversus and Bacillus brevis, and the yeasts Pichia burtonii, Candida didensiae and Rhodotorula rubra (see Abstract). Mulyowidarso et al also teach several species of the family Enterobacteriaceae, namely, E. agglomerans etc also contributed to the ecology of fermentation during the early stages of soaking. Nevertheless, the population achieved by these bacteria were quantitatively significant and would be sufficient to influence

the chemical composition of the soak water and beans (page 44, 3<sup>rd</sup> paragraph). Mulyowidarso et al further teach the growth of microorganisms during the soaking of soybeans is likely to have a significant influence on the quality of the final tempe. Presumably, these microorganisms utilize substances leached from the beans into the water, as substrates for their growth. The metabolic end products of growth, to some extent, would diffuse into the beans thereby affecting their chemical composition. Several researches have already indicated that acidification of the beans may be an important property in controlling the growth of food-borne pathogens and ensuring the microbiological safety of the final tempe (page 44, last paragraph bridging page 45).

Mulyowidarso et al teach microorganisms isolated from soybean includes *Enterobacter agglomerans* (thus a facultative anaerobic gram-negative bacterium which lives in a symbiotic relationship with the plant) (page 40, Table 1). Mulyowidarso et al teach this observation supports the conclusion that soybeans are the main source of microorganisms responsible for bean fermentation during soaking (page 43, last paragraph).

As evidenced by Inagawa et al, lipopolysaccharide (LPS) of plant origin other than that of wheat four was surveyed. Concomitant bacteria possibly extracting in root of farm products can be considered to contribute of LPS of plant origin. Some LPS were derived from concomitant bacteria which had probably come from root. Three predominant bacteria have been isolated and identified; *Pantoea agglomerans*, *Enterobacter cloacae* and *Serratia ficaria*. These LPSs were purified and their chemical compositions were examined (see Abstract). *Pantoea agglomerans* is the most remarkable, since it accounts for 40-70% of all living bacteria in wheat bran and wheat flour and is persistently isolated from all kinds of wheat four produced in districts as different as, Canada, USA, Australia and Japan (page 996, 2nd column, last column).

Inagawa et al also teach, *Pantoea agglomerans* is a species of gram-negative soil bacterial ubiquitously distributed, especially in cotton-seed and wheat, and contributes to the growth of plant by nitrogen fixation and also by release of phosphorus (page 997, 1st column, 1st paragraph) (thus lives in a symbiotic relationship exclusively with a plant). Inagawa et al also teach LPS content in the various plant samples including soybean (page 995, Table 1).

It is noted that since the cited reference teaches the claimed fermented plant extract, it is deemed that the fermented plant extract would inherently have macrophage activation ability even with the presence of polymyxin B (thus the limitation of claim 16 is met).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as a bath agent, a pharmaceutical, or an immunopotentiating agent. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

The combination of Mulyowidarso et al and Inagawa et al do not specifically teach a fermented plant extract powder; neither does the combination teach culturing solely the facultative anaerobic gram-negative bacterium with the edible plant.

Matsuo et al teach Okara tempe (OT), an Indonesian fermented traditional food, which is the fermented okara (insoluble residues of homogenized (thus plant extract powder) soybean, OC) by *Rhizopus oligosporus*, and which is interested in as a new high fiber and low energy soybean food stuff (see Abstract). Matsuo et al also teach commercially available dried OC (30 mesh) (thus plant extract powder) was mixed with water and to adjusted to about pH 5.4 and 75% moisture, then sterilized (page 1189, 1<sup>st</sup> column, 3<sup>rd</sup> paragraph).

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It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use solely Enterobacter agglomerans to culture soybean since Mulyowidarso et al teach significant contributions were made by Klebsiella pneumoniae, Klebsiella ozaenae, Enterobacter cloacae, Enterobacter agglomerans. Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use any single microbial contained in the mixture of Mulyowidarso et al to culture the edible plant.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the fermented homogenized (powdered) soybean product from Matsuo et al since Matsuo et al teach Okara tempe as a new high fiber and low energy soybean food stuff. Since both of the Mulyowidarso et al and Matsuo et al yielded beneficial results in fermented soybean in food industry, one of ordinary skill in the art would have been motivated to combine the teachings of the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "The attached pathway shows *Streptococcus dysgalactiae* decomposes starch into Glycogen, Amylose, Dextrin and a-D-Glucose. (Right hand lower part shows "Starch" and the darker squares are enzymes.)" (page 7, 2<sup>nd</sup> paragraph). Applicant also argues that "Both Mulyowidarso et al. and Matsuo fail to disclose culturing solely a specified

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bacterium equivalent to *Panfoea agglomerans* in a specified circumstance. The claimed invention is to aim at an immunopotentiator obtained inexpensively and efficiently using safe materials as explained in the present published specification [0035]" (page 7, last paragraph). Applicant further argues that "In light of the fact that the combination of cited art fails to culturing solely a specified bacterium equivalent to *Pantoea agglomerans*, the combination cannot make a *prima facie* rejection of obviousness. It is respectfully requested that the rejection be reconsidered and withdrawn" (page 8, 2<sup>nd</sup> paragraph).

This is not found persuasive. It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use solely Enterobacter agglomerans to culture soybean since Mulyowidarso et al teach significant contributions were made by Klebsiella pneumoniae, Klebsiella ozaenae, Enterobacter cloacae, Enterobacter agglomerans. Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use any single microbial contained in the mixture of Mulyowidarso et al to culture the edible plant.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Qiuwen Mi/

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